

Philip Morris USA/Covance

Agenda

Wednesday, April 24, 2002
Boardroom

***Candace Adams, PhD, Smoking Behavior Coordinator, Philip Morris USA**
Hans Carter, PhD, Professor, Department Head, Department of Biostatistics, Virginia Commonwealth University

***Shixia Feng, PhD, Bioanalytical/Organic Chemist, Philip Morris USA**
Chris Gennings, PhD, Associate Professor, Department of Biostatistics, Virginia Commonwealth University

Robert Johnson, PhD, Associate Professor, Department of Biostatistics, Virginia Commonwealth University

***Robin Kinser, PhD, Analytical Coordinator, Philip Morris USA (via audio conference)**

***Bettie Nelson, DrPH, Biostatistical Coordinator, Philip Morris USA**

***Jan Oey, PhD, Project Coordinator, Philip Morris USA**

Hans-Juergen Roethig, MD, PhD, Medical Director, Philip Morris USA

Barbara Zedler, MD, Consultant, Clinical Research

*** Philip Morris USA core team members.**

Rachid Chaouki, MS, Statistician, Data Manager, Covance CRU - Madison

Jenifer Dean, RN, CCRC, CCRP, Associate Director, Clinical Operations, Covance CRU - Madison

Russell Dixon, MD, Medical Director, Covance CRU - Madison

Jayne Garrett, CCRP, Senior Project Coordinator, Clinical Operations, Covance CRU - Madison

John Hunter, MS, Manager, Biostatistics, Covance CRU - Madison

Traci Janisch, CCRP, Supervisor, Medical Writing/Editing, Covance CRU - Madison

Megan Kamps, CCRC, CCRP, Supervisor, Clinical Operations, Covance CRU - Madison

Brigitte Kochan, CCRC, Manager, Client Services, Covance CRU - Madison

Eric Larson, SAS Programmer, Covance CRU - Madison

Mary Larson, RN, CCRC, CCRP, Senior Clinical Project Manager, Covance CRU - Madison

Keith Phillips, Director, Analytical Services, Covance Laboratories - Europe

Jill Schultz, Drug Development Consultant, Covance Consulting Services, Covance Laboratories - Madison

Mary Westrick, PhD, Global Vice President, Clinical Pharmacology, Covance CRU - Madison

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- | | | |
|------------|--|---|
| 7:40 a.m. | Pick up at Hotel | B. Kochan, J. Schultz |
| 8:00 a.m. | Arrival | All |
| 8:15 a.m. | Review of Clinical Performance | J. Dean, M. Larson,
M. Westrick |
| 9:00 a.m. | Protocol Design for Total Exposure Study (TES) | All |
| | 1. Which biomarkers and markers of exposure
will be included in protocol? | |
| | • Which chosen marker is most variable? | |
| | • Type of sample processing required | |
| | 2. Inclusion/exclusion criteria | |
| | 3. Smoking attributes - C. Adams | |
| | • Questionnaire | |
| | • Smoking topography | |
| 12:00 p.m. | Lunch
(Cafeteria) | R. Chaouki, J. Dean,
R. Dixon, J. Garrett,
J. Hunter, T. Janisch,
M. Kamps, B. Kochan,
E. Larson, M. Larson,
J. Schultz, M. Westrick |
| 1:00 p.m. | Discussion of Protocol Design for TES Continued | All |
| | 4. Sampling strategy - B. Nelson | |
| | • Geographical spread | |
| | • Strata | |
| | • Number of visits/volunteer
(i.e., screening + one visit) | |
| | • Sample size estimate | |

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4:00 p.m. Site Identification/Selection/Management

All

1. Review site feasibility/selection process and timeline
 - General mail/fax survey of interest/initiate CDA
 - Receipt of signed CDA
 - Positive response/review of responses
 - Send synopsis/detailed questionnaire/draft contract/budget template
 - Receipt of questionnaire/review of detailed responses/budget
 - Budget/contract negotiations/site indemnification
 - Central IRB - Covance
 - Standard Informed Consent Form
2. Site audits
 - Qualify site, SOP, training records, etc.
 - Assess sample processing capabilities/experience
 - Necessary equipment
3. Monitor visit schedule *not every site*
 - Qualifying visit
 - Initiation (2-day visit, observe sample processing)
 - Interim (5-day visit, i.e., review 20 subject folders/day)
 - Close-out
4. Investigator meeting date/agenda
 - Venue
 - Responsibility
 - Arrangements

*120 subjects/site
10% more subjects
= 600 more
subjects*

Monitor:

① covance Madison = phase 1

*or
② covance N.J. = phase 2*

App. has a monitor. (D.K. 3)

*2 Meetings = ① East
② West 2 weeks later*

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6:00 p.m. Depart Covance for Dinner

B. Kochan, J. Schultz

6:30 p.m. Dinner - Johnny Delmonicos

R. Chaouki, R. Dixon,
J. Garrett, B. Kochan,
M. Larson, K. Phillips,
J. Schultz, M. Westrick

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